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MAR 25 1999

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Dear Ms. Fugere:

FSIS reviewed the March 4, 1998, petition you submitted on behalf of your clients Farm Sanctuary and Michael Baur, asking the Food Safety and Inspection Service (FSIS) to amend the Federal meat inspection regulations to provide that all "downed" livestock be deemed adulterated or condemned and, as a result, removed from the food supply. FSIS has denied your request for the reasons below.

FSIS is not required under the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.) or its regulations concerning the products of a diseased animal, to remove all downed cattle, without exception, from the nation's food supply since FSIS is not bound by the FFDCA's definition of adulteration (21 U.S.C. 342(a)(5)). By law, FSIS must apply the definition of adulteration found in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) to food and food products from cattle, sheep, swine, goats, and equines. The definition of adulteration found in the FFDCA is different from that in the FMIA (compare 21 U.S.C. 342(a)(5) and 21 U.S.C. 601(m)(5) respectively). Unlike the FFDCA, the FMIA does not automatically consider the products of a diseased animal adulterated. Furthermore, under the FMIA, as long as an animal, even a diseased animal, depending upon the disease, has been passed for slaughter, it is possible that the carcass, or a portion of it, may be inspected and passed for human food.

It is obvious that the FFDCA and FMIA regulate different foods and have different areas of concern. Case law has made it clear that the two statutes have independent construction and are not applicable to each other. In *United States v. 2,116 Boxes of Boned Beef*, 516 F.Supp.321, 344 (1981), the court upheld the Department of Agriculture's long standing position that, "There is no requirement in the Federal Meat Inspection Act that any procedures prescribed in the Federal Food, Drug and Cosmetic Act be followed in issuing regulations or taking other actions under the Federal Meat Inspection Act." The court further pointed out that regulations enacted under the FMIA are inapplicable in defining adulteration under the FFDCA. Similarly, definitions under the FFDCA are inapplicable to regulations promulgated and interpreted under the FMIA. Thus, FSIS must apply the definition of adulteration found in the FMIA, not the FFDCA, to livestock brought into a federally inspected slaughter establishment.

You suggest that 9 CFR 301.2(y) means that a non-ambulatory, i.e., downed, animal is a diseased animal. Section 301.2(y) clearly includes both diseased and disabled livestock. Some disabled or non-ambulatory animals are not diseased. Rather, they are affected by a physical condition (e.g., a broken leg) and may not be diseased. Such "downers" may not require any

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partial or complete condemnation. Any non-ambulatory or otherwise disabled livestock that are suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, are handled as "U.S. Suspects" (9 CFR 301.2(xxx)). The carcasses of "U.S. Suspects" are subject to further examination by FSIS veterinary medical officers after slaughter to determine the appropriate disposition. If products made from the carcasses of non-ambulatory animals do not pose a threat to human health, then there is no need to automatically condemn the carcasses simply because they came from "downers." They can be examined, and, if part or all of the meat from them is safe for human consumption, then it can be used for human food.

The FMIA, FSIS regulations, and past practices clearly provide for the slaughter and processing of diseased animals for human food. Such animals may be slaughtered and examined to determine if the meat from their carcasses pose no threat to human health. If they pose no threat, the meat may be passed for human food when the disease or condition does not affect the whole carcass and the diseased part can be removed to make a wholesome product (21 U.S.C. 603, and 9 CFR 301.2(xxx), 309.2). Any livestock showing symptoms of certain diseases must be identified as "U.S. Condemned" and be disposed of according to sections 309.8, 309.13, or 311 (9 CFR 309.4(a)). Section 311 deals with disposal of diseased or otherwise adulterated carcasses or parts and states that the decision as to the disposal of any diseased items not specifically covered on part 311 shall be left to the veterinary medical officer, who is to exercise judgement regarding the disposition of all carcasses or parts to ensure that only wholesome, unadulterated product is passed for human food.

When an FSIS veterinary medical officer is presented with a cow that is unable to rise, a differential diagnosis of the etiology of the syndrome must be made. It is not difficult to distinguish a recumbent cow due to one of the acknowledged "downer cow" syndrome etiologies from one that is affected with a central nervous system (CNS) condition. If proper clinical observations are combined with an adequate history and appropriate laboratory test evaluations, a differential diagnosis is possible in the vast majority of cases. Apparently, you assume that FSIS veterinary medical officers are unable to make a differential diagnosis of "downer cows." Such reasoning contravenes long established principles of veterinary medicine: differential diagnosis and attribution of disease etiology. Moreover, regardless of the diagnosis, all animals with CNS disorders are condemned on antemortem inspection.

Your petition also stated that all downed cattle must be labeled adulterated or condemned and removed from the Nation's food supply because doing so is necessary to prevent the transmission of deadly diseases to humans, particularly bovine spongiform encephalopathy (BSE). However, the consensus of the scientific literature is that BSE does not exist in the U.S. BSE has not been detected in this country, despite active surveillance efforts for several years. Since 1990, nearly 6,500 specimens, from animals in 43 states, have been laboratory tested by an ongoing BSE surveillance system in the U.S. No evidence of BSE (in the form of characteristic lesions) or related transmissible spongiform encephalopathies (TSE) has been seen. In addition, to prevent BSE-contaminated animals or animal products from entering the U.S., severe restrictions exist on the importation of live ruminants and ruminant products from countries where BSE is known to exist.

No cases of BSE have been diagnosed in the United States. In FY 1997, 137,663,099 livestock were slaughtered in USDA inspected establishments. Of those, 358,270 (0.002603 percent) were labeled "U.S. Suspect." Only 827 red meat animals (0.000006 percent) were condemned on antemortem inspection for having a CNS condition. In FY 1998, 1,340 red meat animals (0.000001 percent) were similarly condemned. Regarding the other "serious diseases" listed in your petition that may pose a serious health threat to humans, none, including bovine leukemia virus, bovine immunodeficiency virus, brucellosis, rabies, and Johne's disease, are considered to be meat borne zoonotic diseases. Thus, it would be extremely remote that any of those diseases would be passed on by consumption of red meat animals.

The U.S. has one of the most aggressive BSE surveillance programs in the world, one that is designed to keep the U.S. free of BSE. A United States Department of Agriculture (USDA) BSE Working Group, in coordination with other governments, has been regularly reviewing the available science and implementing appropriate regulatory measures to prevent BSE. These measures include the 1989 ban on cattle and cattle products from countries where BSE has been reported and active inspection, testing and education programs.

USDA has also entered into a cooperative agreement with Harvard University's School of Public Health to analyze and evaluate the Department's current measures to prevent BSE. The two-year study will review current scientific information, characterize the hazards of BSE and other TSE agents to human and animal health, assess the way BSE could potentially enter the U.S., and identify any additional measures that could be taken to protect human and animal health.

Finally, you state that "downed animals represent an extremely small percentage of all livestock slaughtered and banning their use would cause no undue economic hardship." This is incorrect. Condemning all meat and meat products from a carcass with any degree of disease would have a serious economic impact. Using your interpretation of the term "downer," that is, any diseased animal is a downer (based on the Federal Food, Drug and Cosmetic Act and its implementing regulations), there would be a substantial increase in the number of carcasses condemned. For example, a large percent of the livers of livestock (greater than 10 percent) are condemned because of disease conditions. Under your definition, a diseased liver would make an entire carcass adulterated. Such an interpretation would most certainly significantly impact meat availability and prices.

Thank you for allowing FSIS the opportunity to respond to your petition and the questions it raised. You may contact Victoria Levine, Petition Manager, Regulations Development and Analysis Division, at (202) 720-5627, if you have any questions.

Sincerely,

Daniel L. Engeljohn, Ph.D.
Director, Regulations Development and Analysis Division
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facsimile
TRANSMITTAL

To: Jennie Butler
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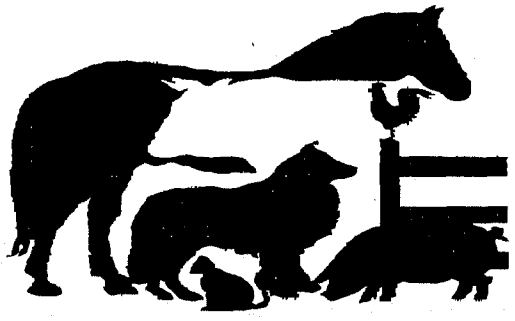
Re: 98P-0151CP
Date: 3-15-01
pages: 5, including this cover sheet.

Signature of originator: Laura Bey

MESSAGES: Jennie
CP 98P-0151
if it is not already
on the Docket



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